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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/574,735	05/18/2000	Lieven DeVeylder	1187-2 CIP	1507
28249	7590	08/11/2005	EXAMINER	
DILWORTH & BARRESE, LLP 333 EARLE OVINGTON BLVD. UNIONDALE, NY 11553			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	
DATE MAILED: 08/11/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/574,735

Applicant(s)

DEVEYLDER ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,5,7-11,14,17,21,24,25,27,30,36-41,43-45,47-50,52-57 and 60-92 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50, 52-57 and 60-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The Amendment filed March 29, 2005 has been entered.

Claims 1, 3-4, 6, 12-13, 15-16, 18-20, 22-23, 26, 28-29, 31-35, 42, 46, 51 and 58-59 are cancelled.

Claims 60-92 are newly added.

Claims 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50, 52-57 and 60-92 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Claim Rejections - 35 USC § 112***

Claims 60-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Newly added claims 60-92 are directed to the introduction into a plant cell of a nucleic acid encoding a plant CKI "wherein the CKI comprises the amino acid sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36, wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one amino acid substitution therein". This limitation does not find support in the specification and therefore constitutes new matter. Newly added claims 89-90 are also directed to the introduction

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into a plant cell of a nucleic acid encoding a plant CKI “wherein the CKI further comprises the consensus sequences set forth in SEQ ID NO:37, SEQ ID NO:38 and SEQ ID NO:39, wherein any one of the sequences set forth in SEQ ID NOS: 37-39 may have one amino acid substitution therein”. This limitation also does not find support in the specification and therefore constitutes new matter.

Applicants’ arguments filed March 29, 2005 have been fully considered but they are not persuasive.

Applicants maintain that support for the subject matter recited in new claims 60-92 may be found throughout the specification, e.g., page 53, line 5, to page 55, line 18 (which includes paragraphs (b) through (9 on page 55). Applicants also maintain that Table 2 of the application provides basis for amino acid substitutions other than those covered by the strict limitations of SEQ ID NO: 34 to SEQ ID NO: 39. Applicants point out that the motifs having the amino acid sequences set forth in SEQ ID NOS: 34-39 do not, in some instances, cover the motifs as they appear in the various CKIs unless one amino acid substitution is taken into account. For example, the CKIs discussed below would not fall within the scope of the consensus sequences SEQ ID NOS. 34, 35, or 36 unless one amino acid substitution is taken into account. (reply page 22)

The Examiner maintains that page 53, line 5, to page 55, line 18 (which includes paragraphs (b) through (9 on page 55) and Table 2 do not support the subject matter recited in new claims 60-92. Page 53, line 5, to page 55, line 18 describes the presence in plant cyclin-dependent kinase inhibitors of previously unrecognized amino acid sequence motifs (SEQ ID NOS: 34-39), and asserts that the current invention includes DNA sequences encoding peptides that are at least 70% identical to SEQ ID NOS: 34-39, but

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page 53, line 5, to page 55, line 18 makes no reference to DNA sequences encoding peptides wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one amino acid substitution therein, or to a plant CKI “wherein any one of the sequences set forth in SEQ ID NOS: 37-39 may have one amino acid substitution therein”. Table 2 presents the conserved amino acid sequence motifs of nine different plant cyclin-dependent kinase inhibitors, and the consensus sequences (SEQ ID NOS: 34-39) derived therefrom, but Table 2 makes no reference to DNA sequences encoding peptides wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one amino acid substitution therein, or to a plant CKI “wherein any one of the sequences set forth in SEQ ID NOS: 37-39 may have one amino acid substitution therein”. The Examiner acknowledges that the motifs having the amino acid sequences set forth in SEQ ID NOS: 34-39 do not, in some instances, cover the motifs as they appear in the various CKIs unless a specific amino acid substitution is taken into account, but maintains that this observation does not support a description of the claimed genus, wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any position therein, and wherein any one of the sequences set forth in SEQ ID NOS: 37-39 may have one unspecified amino acid substitution at any position therein.

With respect to the consensus sequence SEQ ID NO: 34, Applicants submit that *Arabidopsis* CKI2 having the amino acid sequence as set forth in SEQ ID:2, contains one amino acid substitution within this consensus sequence, and that therefore, claims which

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recite SEQ ID NO:34, without accounting for one amino acid substitution, would not cover ICK2, exemplified by the present application. (reply page 22)

The Examiner maintains that the fact that SEQ ID NO:2 contains a single amino acid substitution of a C in place of the first amino acid F in SEQ ID NO:34 does not support a description of the claimed genus, wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any position therein, and wherein any one of the sequences set forth in SEQ ID NOS: 37-39 may have one unspecified amino acid substitution at any position therein.

With respect to the consensus amino acid sequence set forth in SEQ ID NO: 35, Applicants submit that *Arabidopsis* ICK2 contains 1 amino acid substitution within this consensus sequence, and that therefore, claims which recite SEQ ID NO:35, without accounting for one amino acid substitution, would not cover ICK2. Applicants also submit that ICK4 contains 1 amino acid substitution within the consensus sequence of SEQ ID NO:35, and that therefore, claims which recite SEQ ID NO:35, without accounting for one amino acid substitution, would also not cover ICK4. Applicants additionally submit that *Chenopodium* ICK2 contains 1 amino acid substitution within the consensus sequence of SEQ ID NO:35, and that therefore, claims which recite SEQ ID NO:35, without accounting for one amino acid substitution, would additionally not cover *Chenopodium* ICK2. (reply page 23)

The Examiner maintains that the fact that *Arabidopsis* ICK2 contains a single amino acid substitution of G in place of the second amino acid L in SEQ ID NO:35, and

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that ICK4 contains a single amino acid substitution of F in place of the sixth amino acid Y in SEQ ID NO:35, and that *Chenopodium* ICK2 contains a single amino acid substitution of D in place of the penultimate amino acid E in SEQ ID NO:35, does not support a description of the claimed genus, wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any position therein, and wherein any one of the sequences set forth in SEQ ID NOS: 37-39 may have one unspecified amino acid substitution at any position therein.

With respect to the consensus amino acid sequence set forth in SEQ ID NO: 36, Applicants submit that *Arabidopsis* ICK4 contains 1 amino acid substitution within this consensus sequence, and that therefore, claims which recite SEQ ID NO:36, without accounting for one amino acid substitution, would not cover ICK4. Applicants also submit that alfalfa ICK contains 1 amino acid substitution within this consensus sequence, and that therefore, claims which recite SEQ ID NO:36, without accounting for one amino acid substitution, would also not cover alfalfa ICK. (reply pages 23-24)

The Examiner maintains that the fact that *Arabidopsis* ICK4 contains a single amino acid substitution of D in place of the third amino acid E in SEQ ID NO:36, and that alfalfa ICK contains a single amino acid substitution of C in place of the sixth amino acid F in SEQ ID NO:36, does not support a description of the claimed genus, wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any position therein, and wherein

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any one of the sequences set forth in SEQ ID NOS: 37-39 may have one unspecified amino acid substitution at any position therein.

Applicants submit that while in some instances, a CKI will have the consensus sequences as set forth in SEQ ID NOS: 34-36, in other instances a CKI will have the consensus sequences as set forth in SEQ ID NOS: 34-36, taking into account one amino acid substitution as summarized above. Applicants also submit that because plant CKIs often do not exhibit "perfect" consensus sequences corresponding to SEQ ID NOS: 34-36, the present application teaches, e.g., at page 54 last paragraph to page 55, paragraph (f), that plant CKIs may be characterized as having the consensus sequences SEQ ID NOS: 34-39 or else "a peptide that is at least 70% identical thereto." Applicants also submit that the consensus sequences set forth in SEQ ID NOS: 34-39 having one amino acid substitution, although not recited *en haec verba* in the specification, are nevertheless described clearly in the specification, so that one skilled in the art would recognize that Applicants invented the presently claimed methods and compositions including the limitations recited therein. (reply pages 24-26)

The Examiner maintains that the fact that some plant CKIs have the consensus sequences as set forth in SEQ ID NOS: 34-36 taking into account certain specific amino acid substitutions at certain specific positions within the consensus sequences as set forth above does not support a description of the claimed genus, wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any position therein, and wherein any one of the



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sequences set forth in SEQ ID NOS: 37-39 may have one unspecified amino acid substitution at any position therein.

Claims 2, 5, 7, 11, 14, 17, 21, 25, 27, 30, 36, 54 and 55, and claims 8-10, 24, 37-41, 43-45, 47-50, 56 and 57 dependent thereon, remain rejected, and claims 60-86 and 89-92 are rejected, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record.

Applicants' arguments filed March 29, 2005 have been fully considered but they are not persuasive.

Applicants interpret the Examiner's position as asserting that despite the fact that the specification provides literal support for the recitation in the claims of plant CKIs comprising amino acid sequences at least 70% identical to the sequences set forth SEQ ID NOS:34-39, and despite the fact that the specification provides examples of plant CKIs comprising the plant CKI consensus sequences discovered by the present invention, which sequences are at least 70% identical to the sequences set forth SEQ ID NOS:34-39 which function in the methods and compositions of the present invention, the written description requirement is not met by the present claims. Applicants also maintain that the Examiner's assertion at page 4, lines 15-18 that "neither the specification nor the prior art describe plant CKIs that comprise 2 to 3 unspecified amino acids at any unspecified position in each motif" is unclear. Applicants additionally point out that both

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the specification and prior art certainly disclose different CKIs having at least 70% sequence identity to the disclosed sequence motifs SEQ ID NOS: 34-39. In many of these exemplified CKIs, one amino acid residue is substituted in the sequences set forth in SEQ NOS: 34-39. (reply pages 26-28)

The Examiner maintains that a mere assertion in the specification that the current invention includes DNA sequences encoding peptides that are at least 70% identical to SEQ ID NOS: 34-39 (i.e. at pages 54-55) does not describe the structure of peptides that are at least 70% identical to SEQ ID NOS: 34-39. It was to this issue that the Examiner's assertion that neither the specification nor the prior art describe plant CKIs that comprise 2 to 3 unspecified amino acids at any unspecified position in each motif was directed, since peptides that are at least 70% identical to SEQ ID NOS: 34-39 would be expected to have 2 to 3 amino acids substituted at varying positions in SEQ ID NOS: 34-39. The Examiner further maintains that the plant CKIs exemplified in the specification do not appear to comprise sequences are at least 70% identical to the sequences set forth SEQ ID NOS:34-39.

Applicants maintain that the Examiner's statement at page 5, last line, to page 6, line 2, that "one skilled in the art would not know on the basis of the disclosure which of the 20 different amino acid residues would occupy which of the eight of ten available positions in each of the recited motifs that plant CKIs comprise" is not relevant in a proper written description determination since predictability is not the legal standard or test for rejections under the written description requirement. See *Ex parte Yuejin Sun*, 2003 Pat. App. LEXIS 65 (Bd. Pat. Appl. & Inter., February 27, 2003), provided herewith

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as Exhibit A. Applicants also maintain that a skilled artisan would not be faced with no knowing which of the 20 different amino acids would occupy which of the eight to ten available positions in each of the recited motifs, but rather a skilled artisan having in hand the consensus sequences provided by the present application and set forth in SEQ ID NO:34-39 as well as other teachings provided by the present application, would have known that other plant ICKS may be identified and used in the methods and compositions of the present invention by using the consensus sequences provided by SEQ ID NOs:34-39 as a guide and that such identified other plant ICKS might certainly have sequences at least 70% identical to any of SEQ ID NOs:34-39. (reply page 28)

The Examiner maintains that the outstanding written description rejection makes no reference to predictability. The observation that one skilled in the art would not know on the basis of the disclosure which of the 20 different amino acid residues would occupy which of the eight of ten available positions in each of the recited motifs that plant CKIs comprise merely indicates that one skilled in the art could not visualize on the basis of the disclosure which of the 20 different amino acid residues would occupy which of the eight of ten available positions in each of the recited motifs that plant CKIs comprise.

Additionally, Applicants' reliance on *Ex parte Yuejin Sun* is inappropriate, since the opinion in support of that decision was not written for publication and is not binding precedent of the Board. Furthermore, whether a sequence is described is not dependent on whether the specification provides an enabling disclosure. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), which discusses the description of a claimed human cDNA sequence based on the disclosure of a rat cDNA sequence and a method for obtaining the human cDNA sequence:

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The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example, however, provides only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. (*Lilly*, 43 USPQ2d at 1405)

In the instant case using the consensus sequences as well as other teachings provided by the present application to make and use other undisclosed plant ICKS does not describe other undisclosed plant ICKS.

Applicants interpret the Examiner's position as asserting that Applicants are only entitled to methods and compositions comprising CKIs having the specific substitutions disclosed. In this regard Applicants maintain that the present application more than adequately described a representative number of species presently embraced by the claims, and Applicants point to the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶ 1 Written Description Requirement, which make clear on page 1106 that description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. (reply pages 28-29)

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The Examiner's position is directed only to the rejected claims. In this regard the Examiner maintains that the disclosed species are not representative of the claimed genus, wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any position therein, and wherein any one of the sequences set forth in SEQ ID NOS: 37-39 may have one unspecified amino acid substitution at any position therein.

For the record, Applicants also correct the Examiner's characterization of plant CKIs having the consensus sequences provided by the present invention. Applicants point out that the statement on page 4 of the Office Action that "SEQ ID NO:35 may specifically vary at one of two positions" is incorrect. Plant ICKS are known to vary at 4 positions in the consensus sequence SEQ ID NO:35. See Table 2 which clearly shows that the 8 amino acid sequence motif may vary at position 2 (e.g., in ICK2), position 6 (e.g., ICK4), position 7 (e.g., ICK6, ICK7, and *Chenopodium* ICK), and in position 8 (e.g., Alfalfa ICK). (reply page 29)

The Examiner agrees with Applicants' correction on this point. Table 2 shows that the 8 amino acid sequence motif may vary at position 2 (e.g., in ICK2), position 6 (e.g., ICK4), position 7 (e.g., ICK6, ICK7, and *Chenopodium* ICK), and in position 8 (e.g., Alfalfa ICK).

Applicants also point out that the statement on page 4 of the Office Action that "SEQ ID NO:36 may specifically vary at one of two positions" is incorrect. Table 2 of the application clearly indicates, however, that plants vary in three different positions in

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SEQ ID NO:36. For example, alfalfa ICK varies at position 6, ICK4 and ICK7 both vary at position 3, and ICK6 varies at position 5. (reply page 29)

The Examiner agrees with Applicants' correction on this point. Table 2 shows that the 8 amino acid sequence motif may vary at position 6 (e.g., in alfalfa ICK), position 3 (e.g., ICK4 and ICK7), and in position 5 (e.g., ICK6).

Applicants also point out that the statement on page 7, lines 3-5 of the Office Action should indicate that for SEQ ID NO:35, six (not four) of the disclosed plant CKIs have a consensus sequence that varies from the consensus sequence of SEQ ID NO:35, and each varies by one amino acid at four (not two) different locations. The Examiner apparently did not consider alfalfa ICK and ICK2. (reply pages 29-30)

The Examiner agrees with Applicants' correction on this point. Table 2 shows that six of the disclosed plant CKIs have a consensus sequence that varies from the consensus sequence of SEQ ID NO:35.

Applicants also point out that the statement on page 7, lines 3-5 of the Office Action should indicate that for SEQ ID NO36, four (not three) of the nine disclosed plant CKIs have a consensus sequence that varies from the consensus sequence of SEQ ID NO:36 and each varies by one amino acid substitution at three (not two) different locations. Applicants direct the Examiner to ICK6, which was apparently not considered by the Examiner. (reply page 30)

The Examiner agrees with Applicants' correction on this point. Table 2 shows that four of the nine disclosed plant CKIs have a consensus sequence that varies from the

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consensus sequence of SEQ ID NO:36 and each varies by one amino acid substitution at three different locations.

Applicants also point out that the statement on page 7, line 2, four (not three) of the nine disclosed plant CKIs have a consensus sequence that is less than 100% identical to the consensus sequence set forth in SEQ ID NO:36. Again, the Examiner apparently did not consider ICK6.

The Examiner agrees with Applicants' correction on this point. Table 2 shows that four of the nine disclosed plant CKIs have a consensus sequence that is less than 100% identical to the consensus sequence set forth in SEQ ID NO:36.

Regarding the Examiner's statement respect to the rice plant CKI ICK2 not supporting the description of the plant CKIs recited in the claims because the rice plant CKI ICK2 was identified after the present application was filed, and the written description requirement must be met at the time of filing, Applicants submit that the showing made in the rule 132 declaration submitted previously, that the rice plant CKI ICK7 was identified following the teachings of the present invention, albeit after the present application was first filed, is appropriate since it demonstrates how one skilled in the art relied on the teachings of the present application as originally filed. Thus, while it is true that a later dated disclosure cannot supplement an insufficient disclosure in a prior dated application, the use of later publications (in this case, the later disclosure of rice CKI ICK2 submitted as part of the Rule 132 declaration) as evidence of the state of the

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art existing on the filing date of the application is appropriate. See e.g. *In re Hogan* 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977). (reply pages 30-31)

Applicants also point to the declaration under 37 C.F.R. §1.132 executed by Dr. Catherine Bergounioux, submitted herewith. As stated in paragraph 5 of the declaration, Dr. Bergounioux is co-author of an article published in the Journal of Cell Science (Jasinski S. et al. The CDK inhibitor NtKIS1a is involved in plant development, endoreduplication and restores normal development of cyclin D3; 1-overexpressing plants. J Cell Sci. 2002 Mar 1;115(Pt 5):973-82), provided at Exhibit B of the declaration. As discussed in paragraph 6 of the declaration, the published article describes a CKI from tobacco, NtKIS1a, and the phenotypic characteristics of *Arabidopsis* plants transformed with the corresponding NtKIS1a gene under the control of the constitutive cauliflower mosaic virus 35S promoter. The transformed 35S::NtKIS1a plants showed reduced growth with smaller organs that contained larger cells; reduced CDK kinase activity, serrated leaves and reduced endoreduplication. These phenotypic characteristics are the same as those described in the above-identified application and as described in a publication by De Veylder L. et al. (Functional analysis of cyclin-dependent kinase inhibitors of Arabidopsis. Plant Cell. 2001 Jul;13(7):1653-68).

As stated in paragraph 7 of the declaration, Applicants point out that it is Dr. Bergounioux's scientific belief that other CKI proteins could also be used to achieve the same results. Her basis for this statement is her finding that the tobacco CKI, NtKIS1a, comprises a first sequence motif which is identical to the sequence set forth in the above-identified application as SEQ ID NO:34 as well as a second sequence motif comparable but not identical to the consensus sequence set forth in the above-identified application as



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SEQ ID NO:35 and a third sequence motif comparable but not identical to the consensus sequence set forth in the above-identified application as SEQ ID NO:36. Specifically, in NtKISla (NCBI Accession Number (2AC82732), the sequence comparable to SEQ ID NO: 35 is: PSXGRYEW and the sequence comparable to SEQ ID NO: 36 is:

EIEDFFAVRQ. The consensus sequences of SEQ ID NO: 34, SEQ ID NO: 35 and SEQ ID NO: 36 (and also of consensus sequences SEQ ID NO: 37, SEQ ID NO: 38 and SEQ ID NO: 39) were also described in Table 1 of De Veylder et al. (see Exhibit C of the declaration). Table 1 of De Veylder et al. is identical to Table 2 of the above-identified application except that Motif 1 of Table 1 is equivalent to Motif 2 or SEQ ID NO: 35 of Table 2 of the present application, and Motif 5 of Table 1 is equivalent to Motif 6 or SEQ ID NO:39 of Table 2 of the present application. As taught on page 53 of the above-identified application, as well as column 1, page 1655 of the De Veylder publication provided at Exhibit C of the Bergounioux declaration, the three domains located at the extremity of the C-terminal part of the proteins are shared by all CKIs and are therefore important in identifying plant CKIs. It is Dr. Bergounioux's considered scientific opinion therefore, that one skilled in the art following the teachings of the above-identified application as of its filing date, as well as the literature extant at the time of filing, would have known that NtKISla was a CKI due to the presence of these three consensus sequences (SEQ ID NOs:34-36). These three consensus sequences were first provided in the written description of the present application. (reply pages 31-33)

The Examiner maintains that sequences described after the filing date of the instant application (**May 18, 2000**) cannot be used to support a description of the claimed sequences. The rice plant CKI ICK2 does not support the description of the plant CKIs

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recited in the claims because the rice plant CKI ICK2 was identified after the present application was filed. Likewise the tobacco plant CKI NtKIS1a does not support the description of the plant CKIs recited in the claims because the tobacco plant CKI NtKIS1a was identified after the present application was filed. The Examiner also maintains that Applicants' reliance on *In re Hogan* is inapposite to the outstanding rejection, as none of the claims at issue in *In re Hogan* were rejected under 35 USC 112, first paragraph, for inadequate written description. The claims at issue in *In re Hogan* were rejected under 35 USC 112, first paragraph, for lack of enablement only. In this regard the Examiner reiterates that whether a sequence is described is not dependent on whether the specification provides an enabling disclosure. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), which discusses the description of a claimed human cDNA sequence based on the disclosure of a rat cDNA sequence and a method for obtaining the human cDNA sequence:

The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example, however, provides only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. (*Lilly*, 43 USPQ2d at 1405)

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In the instant case using the consensus sequences as well as other teachings provided by the present application to make and use other undisclosed plant ICKS does not describe other undisclosed plant ICKS.

Applicants finally submit that they have repeatedly demonstrated much more than a conclusion that they were in possession of the presently claimed invention as of the filing date. Applicants point out that they have provided a written description of the genus of plant CKIs sufficient to distinguish it from other materials. Applicants have further repeatedly demonstrated during prosecution of this application, that CKIs which bind a plant cyclin-dependent kinase having a PSTAIRE cyclin-binding motif, wherein the CKIs comprise the amino acid sequences as set forth in SEQ ID NOs:34, 35, and 36 or else comprise amino acid sequences having at least 70% identities to the amino acid sequences as set forth in SEQ ID NOs:34, 35, and 36, or alternatively amino acid sequences corresponding to SEQ ID NOs: 34-36 having one amino acid substitution therein, may be used for decreasing or increasing cyclin dependent kinase activity in a plant, thereby obtaining plants with various phenotypes as presently claimed. Applicants maintain that the Examiner has failed to indicate why one of ordinary skill in the art, who is in possession of the consensus sequences set forth in SEQ ID NOs:34-39 as well as sequences at least 70% identical to SEQ ID NOs:34-39, would be unable to recognize, upon reading the present application, that Applicants invented the claimed subject matter. (reply pages 33-34)

The Examiner reiterates that an assertion that Applicants were in possession of the claimed subject matter does not substitute for a description of amino acid sequences

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at least 70% identical to the disclosed conserved amino acid motifs of SEQ ID NOS:34-39, or that have one unspecified amino acid substitution at any position in SEQ ID NOS:34-39, because a showing of possession alone does not satisfy the written description requirement. See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1617:

Application of the written description requirement, however, is not subsumed by the "possession" inquiry. A showing of "possession" is ancillary to the *statutory* mandate that "[t]he specification shall contain a written description of the invention," and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention. After all, as indicated above, one can show possession of an invention by means of an affidavit or declaration during prosecution, as one does in an interference or when one files an affidavit under 37 C.F.R. § 1.131 to antedate a reference. However, such a showing of possession alone does not cure the lack of a written description in the specification, as required by statute.

The Examiner also reiterates that whether a sequence is described is not dependent on whether the specification provides an enabling disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 89-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 89-90 are indefinite in the recitation of "may have". It is unclear whether the claim in fact encompasses sequences having one amino acid substitution therein.

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***Double Patenting***

Claim 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50 and 52-57 remain rejected, and claims 60-92 are rejected, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,710,227, issued March 23, 2004 from U.S. Application No. 09/526,597, for reasons of record.

The Office acknowledges Applicant's statement filed November 19, 2003 in response to the prior provisional rejection of claims 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50 and 52-57 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9, 13-19, 21-23, 43-48 and 51-52 of copending Application No. 09/526,597, now U.S. Patent No. 6,710,227, submitting that a terminal disclaimer will be submitted upon allowance of the claims presently under consideration in this application.

Claim 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50 and 52-57 remain provisionally rejected, and claims 60-92 are provisionally rejected, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-9 and 13-23 of copending Application No. 10/688,291, for reasons of record.

The Office acknowledges Applicant's statement filed March 29, 2005 submitting that upon allowance of the claims under consideration in this application, an appropriate action will be taken in order to obviate the provisional double patenting rejection.

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***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins  
Primary Examiner  
Art Unit 1638

CC

  
7/25/05